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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,270

03/17/2005

Stephen John Brough

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4129

26164 7590 02/29/2008

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

02/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/528,270	<b>Applicant(s)</b> BROUGH ET AL.	
	<b>Examiner</b> SUSANNA MOORE	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/27/07</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's argument, see Remarks, filed 12/27/2007, with respect to the rejection(s) of claim(s) 1 and 9 have been fully considered. Since no new rejections are being made, this is a Final Office Action.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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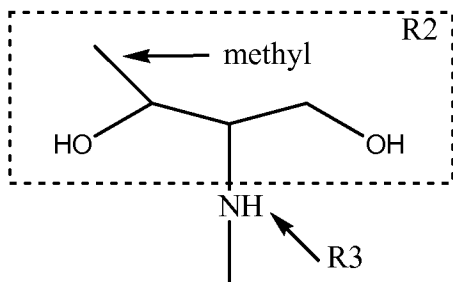
the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Willis et. al. (WO 01/25242, US equivalent is 6790850).

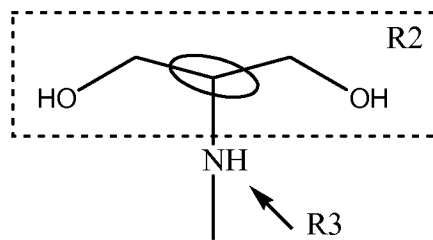
The instant Application teaches a compound of formula (I) and the process of making said compound, 5-[[2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)propyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one.

Willis et. al. claims the following specie, 5-[[2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, and a method of synthesizing said specie. See claim 4 for the specie and the process in claim 7.

The difference between the instant invention and the reference is at the 7-amino substituent. Although the conflicting claims are not identical, they are obvious variants because the specie found in claim 4 of the referenced patent, 5-[[2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

This is just one specie of the many that renders the compounds obvious over the instant Application.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

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disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Applicant traverses the above rejection by stating the instant invention is claiming a particular stereoisomer, which has two stereocenters, and as such, this compound is not an obvious variant to the referenced compound.

This is not found persuasive. The reference encompasses all geometric and optical isomers, see column 3, line 1. Furthermore, a particular stereoisomer is close enough structurally to render a different stereoisomer obvious. The M.P.E.P. states (2144.08): “In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) (“When chemical compounds have very close’ structural similarities and similar utilities, without more a prima facie case may be made.”). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458

F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).” Moreover, for an obviousness-type rejection the species do not have to meet the requirements of the claims, the specie must only render obvious said claims.

Thus, the rejection is maintained.

The provisional rejection of claims 1 and 9 under 35 U.S.C. 103(a) as being obvious over copending Application No. 10863995 which has a common assignee with the instant application is withdrawn. This case is a related case with the same disclosure as the '850 patent cited above. Thus, the response is the same as that indicated above.

### ***Double Patenting***

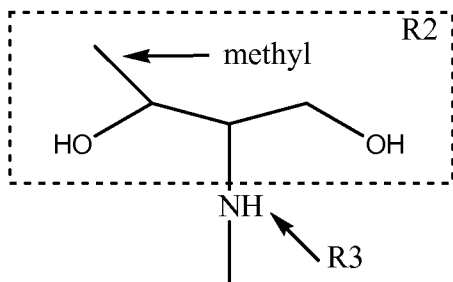
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

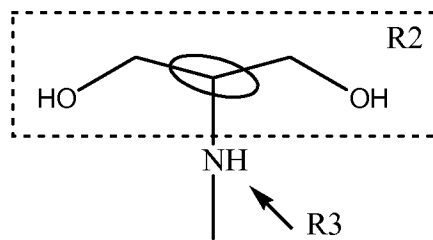
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,790,850. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 4, column 39, lines 54-56, of the referenced patent, 5-[[2,3-difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl)ethyl]amino]thiazolo[4,5-d]pyrimidin-2(3H)-one, is a structural homolog of the compound found in claim 1 of the instant application. The only difference between these compounds is the substitution at R2, the R2 substituent has a hydrogen versus Applicants methyl group, which is illustrated with the structures below. Thus, the compounds are not patentably distinct.





R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

Since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The MPEP 2144.09 states “Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH<sub>2</sub>- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

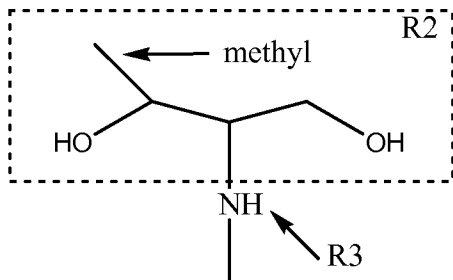
This is just one specie of the many that renders the compounds not patentably distinct over the instant Application.

Applicant traverses the above rejection by stating, the same argument as that provided above for the 103 art rejection. The response to the traversal is also the same as that stated above.

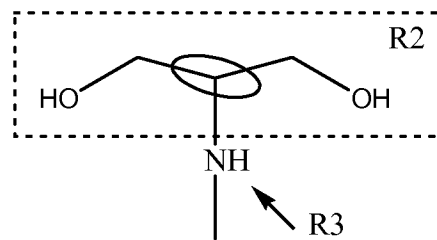
Claims 1 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-26 of copending Application No. 10/863995. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound in claim 23, the seventh specie listed, 5-[(2,3-

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difluorophenyl)methyl]thio]-7-[[2-hydroxy-1-(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one is a homolog of the compound in instant claim 1, formula (I), 5-[[[(2,3-difluorophenyl)methyl]thio]-7-[1,1-(di(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3 H)-one. The only difference between these compounds is a hydrogen versus Applicants methyl group, which is illustrated below. The same argument used above addresses this scenario.



R2 and R3 with attached nitrogen of the current case



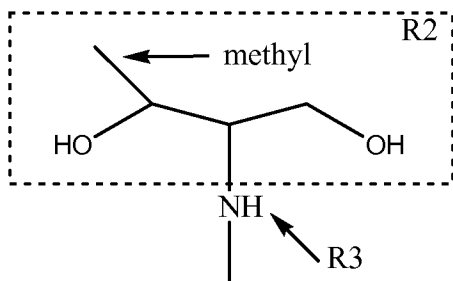
R2 and R3 with the attached nitrogen of the co-pending case

The instant Application is drawn to a method of treating arthritis with said compounds. The copending Application discloses the compounds as antiarthritic agent. See page 13. This is just one of the many obvious species that renders said claims obvious over the copending Application.

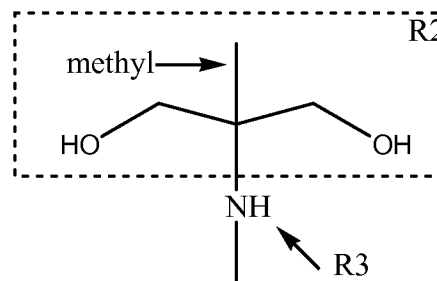
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant used the same traversal for this rejection as that indicated above. Thus, the response is the same as that indicated above. Thus, the rejection is maintained.

Claims 1 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of copending Application No. 10528316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specie found in claim 1 of formula (I) of the co-pending application, 5-[[[(2,3-difluorophenyl)methyl]thio]-7-[1,1-(di(hydroxymethyl))ethyl]amino]thiazolo [4,5-d]pyrimidin-2(3H)-one, is a positional isomer of the specie found in claim 1 of the instant application. The difference between the two compounds is the location of the methyl group illustrated below. The same homology/positional isomer argument used above applies here.



R2 and R3 with attached nitrogen of the current case



R2 and R3 with the attached nitrogen of the co-pending case

Both Applications claim the same process in claim 9 of the instant Application and the copending Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant traverse the above rejection by stating claim 1 recites a particular stereoisomer having 2 stereocenters, as opposed to a compound of undesignated stereochemistry. Applicant goes on to state that the copending Application recites a particular monosodium salt of the compound illustrated in the above rejection as opposed to the non-salt or free form. Furthermore, Applicant has submitted a 1.132 Affidavit with unexpected results. However, the instant Application claims in claim 1, pharmaceutically acceptable salts. The Berge et. al. (J. of Pharm. Sciences, 1977, pages 1-19). teaches sodium as one of the most frequent cationic salts used/made prior to 1977, see Table 1 and the left-hand column, lines 12-13. Moreover, as previously mentioned, the M.P.E.P. states (2144.08): "In fact, similar properties may normally be presumed when compounds are very close in structure. *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also *In re Grabiak*, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would have been obvious. *Dillon*, 919 F.2d at 697-98, 16 USPQ2d at 1905; *In re Wilder*, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972)." Moreover, for an obviousness-type rejection the species do not have to meet the requirements of the claims, the specie must only render obvious said claims.

Thus, the rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/  
Examiner, Art Unit 1624

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624